

# UC Davis Policy and Procedure Manual

## Chapter 290, Health and Safety Services

### Section 55, Biological Safety

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Responsible Department: Environmental Health and Safety

Source Document: National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules

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#### I. Purpose

This section outlines the policy and procedures governing the safe use of infectious biological agents, recombinant DNA/RNA, and the propagation and release of recombinant organisms, including plants, animals, and microbial agents.

#### II. Policy

- A. Biological agents shall be used safely to protect the health, safety, and well-being of the campus community and neighboring populations; the wild and domestic plants and animals maintained on UC Davis property and surrounding areas; and the environment.
- B. All University research involving recombinant DNA molecules (rDNA) shall be conducted in compliance with NIH Guidelines for Research Involving Recombinant DNA Molecules (the NIH Guidelines) regardless of the fund source.
- C. Any work with biohazardous materials that customarily requires Biosafety Level 4 (BSL4) containment is prohibited.

#### III. Approvals

- A. The following activities require approval of a Biological Use Authorization (BUA) by the Biological Safety Administrative Advisory Committee (BSAAC).
  1. Research activities that involve the use of recombinant DNA technology or products (see the NIH Guidelines, Section III and Appendices).
    - a. Approval is required before initiation of work, regardless of Risk Group (biosafety level) or applicable section of the NIH Guidelines.
    - b. The NIH Guidelines provide further information on required federal agency approval of certain types of projects that involve recombinant DNA technology.
  2. Human gene transfer/gene therapy trials at UCDMC (see the NIH Guidelines, Appendix M).

Approval must be obtained after the NIH Recombinant DNA Advisory Committee has reviewed the project, but before any patients are enrolled.
  3. Research and other activities involving the use of microbial agents listed as Risk Group 2 or 3 (see NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL, fifth edition or later), the NIH Guidelines, or the UC Davis Biosafety Manual), or agents that are customarily handled at Biosafety Level 2 or 3 regardless of Risk Group.
    - a. Use must be approved before transfer of agents to campus, UCDMC, or affiliated laboratories and initiation of work.
    - b. Importation of human pathogenic microbial agents also requires Centers for Disease Control approval.
    - c. Importation or interstate transfer of livestock or agricultural crop pathogenic microbial agents also requires USDA-Animal and Plant Health Inspection Service

(APHIS) approval.

- d. The activity shall be reviewed by the BSAAC prior to review by government agencies requiring a permit for the activity.
4. Research activities involving the release of noxious or genetically engineered organisms, including animals, plants, and microbial agents, into the environment.
  - a. These activities also require approval by the USDA.
  - b. The activity shall be reviewed by the BSAAC prior to review by the USDA or any other government agency requiring a permit for the activity.
5. Research and other activities that involve in vivo production and subsequent extraction of toxins from the natural sources (including unicellular, multicellular, plant, invertebrate and vertebrate sources).
  - a. The activities require BSAAC review and approval before the toxin-secreting agents can be transferred to the Davis campus, UCDCM, or a affiliated laboratory, and before work can be initiated.
  - b. Work with toxin-producing plant and animal species that does not involve toxin extraction or isolation does not require BSAAC review.
  - c. Work with toxin-producing microbial agents requires BSAAC review and approval regardless of whether toxins are intentionally being recovered.
- B. The following activities are regulated under OSHA Blood Borne Pathogen and Medical Waste Management statutes, and require approval of a BUA by the BSAAC only as noted below.
  1. Activities involving the use of human body fluids, human primary cell cultures, established human cell lines, and unfixed human tissues.
    - a. These activities require the completion of a Bloodborne Pathogen Exposure Control Plan as part of the Injury Illness Prevention Plan (IIPP).
    - b. These materials are always handled at Biosafety Level 2 or greater.
    - c. Initial training and annual refresher training in biological safety and bloodborne pathogen exposure control are required.
    - d. Activities involving tissues or cells known or suspected to be infected or contaminated with any biohazardous agent require approval of a BUA by the BSAAC.
  2. Activities involving the use of nonhuman primate body fluids, nonhuman primate primary cell cultures, established nonhuman primate cell lines, and unfixed nonhuman primate tissues.
    - a. Initial and annual training in biological safety and documentation is required as part of the IIPP.
    - b. These materials are always handled at Biosafety Level 2 or greater.
    - c. Activities involving tissues or cells known or suspected to be infected or contaminated with any biohazardous agent require approval of a BUA by the BSAAC.
  3. Activities that generate medical waste (i.e., human tissues, materials contaminated with human tissues including body fluids, potential or known human infectious agents, human pathogenic agents, or toxin-producing agents including zoonotic agents).
    - a. Training and completion of a Medical Waste Management Plan is required as part

of the IIPP.

- b. Activities involving tissues or cells known or suspected to be infected or contaminated with any biohazardous agent require approval of a BUA by the BSAAC.

#### **IV. Responsibilities**

##### **A. Vice Chancellor—Administration**

On the advice of the BSAAC, terminates or restricts any project or teaching program not in compliance with this policy.

##### **B. Biological Safety Administrative Advisory Committee (BSAAC)**

The BSAAC Standard Operating Procedures, Definitions, Delegations of Authority, background information, and training documents are included in the Biological Safety Administrative Advisory Committee handbook, available for review at the Environmental Health and Safety main office.

1. Acts as the NIH-mandated Institutional Biosafety Committee for UC Davis.
2. Reviews and approves research proposals and other activities involving any of the following:
  - a. Recombinant DNA technology.
  - b. Human gene transfer/gene therapy.
  - c. Biohazardous agents (i.e., any viable infectious, pathogenic, or toxin-producing agent, prion, toxin, or nucleic acid construct including genetic locus, gene combination, gene, nucleic acid sequence, gene vector, expressed foreign (recombinant-derived) protein, or transformed or otherwise genetically manipulated host that has potential to affect the health of humans, animals, plants, or ecosystems).
3. Determines the appropriate containment and handling (Biosafety) level (BSL) for all projects reviewed in the BUA process.
4. Denies approval for any project that cannot be undertaken safely at UC Davis facilities.
5. Approves campus biological safety-related practices (e.g., spill handling, laboratory hygiene and conduct, standard practices, emergency response procedures).
6. Reviews updates to compliance documents (e.g., Campus Biosafety Manual).
7. Recommends modification, suspension, or termination of projects when it is in the best interest of the health and safety of the campus and surrounding community.
8. Reviews and recommends policies and procedures for health surveillance of individuals involved in programs using biohazardous materials.
9. Refer prohibited experiments (see the NIH Guidelines III.A) to the NIH Recombinant DNA Advisory Committee for review.
10. Reports adverse events and violations of the NIH Guidelines to the NIH Office of Biotechnology Activities unless it determines that the principal investigator involved has already made such a report (e.g., adverse events in gene therapy trials).

##### **C. Biological Safety Officer**

1. Administers the campus biological safety program (see also the NIH Guidelines, Section IV.B.3.c).

- a. Performs periodic inspections to ensure that laboratory standards are rigorously followed.
  - b. Reports any significant problems, adverse events, violations of the NIH Guidelines, or any significant research-related accidents or illness to the BSAAC (unless a report has already been filed by the Principal Investigator).
  - c. Develops emergency plans for handling accidental spills and personal contamination and investigating laboratory accidents involving recombinant DNA research.
  - d. Provides advice on laboratory security.
  - e. Provides technical advice to Principal Investigators and to the BSAAC regarding research safety procedures.
2. Acts as a voting member of the BSAAC.
  3. Reviews BUA applications and prepares them for submission to the BSAAC.
  4. Reviews government agency permit applications that involve biohazardous materials and prepares them for submission to the BSAAC.
  5. Manages the business of the BSAAC under the NIH Guidelines.
  6. Provides guidance in the development, operations, and management of containment (Biosafety Level 3) laboratories and certifies the safety of these laboratories before they become operational and annually thereafter.
  7. Oversees the Containment Laboratory Operations Work Group.
  8. Reviews Animal Care and Use Protocols when proposed work with animals involves biohazardous agents.
    - a. Determines whether project requires approval of a BUA.
    - b. Reports the PI and project BUA status to the Institutional Animal Care and Use Committee.
    - c. Recommends appropriate modifications of the Animal Care and Use Protocol to reduce biohazard risk.
  9. Reviews research proposals from the Office of Research, Sponsored Programs (SPO) when the work involves biohazardous agents.
    - a. Determines whether the project requires approval of a BUA.
    - b. Notifies SPO and the PI of the status of the BUA, results of the review, and provides approved BUA number.
  10. Manages the select agent program and serves as the Responsible Official or Alternate Responsible Official as defined in 42 CFR Section 73.
  11. Approves purchases of equipment for working with biohazardous materials, such as biosafety cabinets, glove boxes, and other containment equipment.
  12. Provides training for safe handling practices involving biohazardous materials.
  13. Provides direct oversight of campus microbiological diagnostic and teaching laboratories, including archival collections.
  14. Documents zoonosis incidents (animal-to-human disease transfer) and laboratory-acquired infections.

15. Ensures continual accuracy of Campus Biosafety Manual.

D. Department Head

1. Reviews and provides department level approval of BUA and government agency permit applications in advance of submission to BSAAC.
2. Ensures resources necessary to control potential hazards, appropriate training, and enforcement of policies and procedures.

E. Principal Investigator (PI)

1. Conducts work in compliance with all Federal, State, and University requirements.
2. Ensures the safe operation of laboratory or other facility.
3. Prepares, submits, and obtains approval of a BUA and government agency permits as required (see II, above).
4. Amends applications for existing BUA or permits and submits for review by BSAAC when change of conditions are to take place (e.g., procedures, personnel, location, or biological agents are to be changed or modified) prior to enacting the change.  
Amendment must be approved prior to the change.
5. Provides initial and annual documented training of laboratory personnel and students for existing projects and prior to initiation of new projects (see II, above).
6. Reports adverse events or research accidents involving biohazardous agents to the Biological Safety Officer or to the BSAAC.
7. Ensures compliance with the Employee Health Physician's recommendations associated with projects.
8. Ensures certification of all Class II and III biological safety cabinets at the time of installation, annually, after the filter or motor is replaced or repaired, or when a cabinet is moved.
9. Ensures certification of all in-place building HEPA filters at the time of installation, annually, or when a filter is replaced or repaired.

F. Employees and Students

Trained research staff, graduate students, postdoctoral fellows, and undergraduate students involved in supervised research or enrolled in laboratory courses involving the use of biohazardous materials shall take the following precautions to protect themselves:

1. Become familiar with the project and its associated potential hazards.
2. Follow the safety procedures outlined in the BUA, the UC Davis Biosafety Manual, and in training provided by the PI.
3. Use provided safety equipment.
4. Report unsafe or hazardous situations immediately to the laboratory supervisor, instructor, or PI.
5. Participate in mandated medical surveillance programs.
6. Participate in required safety training and ensure understanding of all elements of the training and instruction.
7. Follow campus medical waste and hazardous waste disposal procedures.

G. Employee Health Physician

1. Acts as a voting member of the BSAAC.
  2. Determines the level of medical surveillance of personnel/students associated with projects.
  3. Provides consultation to Cowell Student Health Center to assure appropriate medical surveillance of students.
- H. Cowell Student Health Center
- In consultation with the Employee Health Physician, provides medical surveillance of students associated with projects involving biohazardous materials or animals.
- I. Environmental Health and Safety (EH&S)
1. Provides consultation as requested.
  2. Audits project facilities prior to approval of BUA and annually thereafter.
  3. Verifies certification of all Class II and III biological safety cabinets at the time of installation, annually, after the filter or motor is replaced or repaired, or when a cabinet is moved.
  4. Verifies certification of all in place building HEPA filters at the time of installation, annually, and when a filter is replaced or repaired.
  5. Provides training in biological safety.
  6. Provides assistance to PIs in training laboratory personnel.
- J. Director—EH&S
- Acts as Alternate Responsible Official or Responsible Official for the Select Agent program as described in 42 CFR Section 73.
- K. Institutional Animal Care and Use Committee (IACUC)
1. Collaborates with BSAAC to ensure that animal care staff and other personnel are not exposed unnecessarily to experimental biological agents.
  2. Submits Animal Care and Use Protocols that indicate biohazardous agents to the Biological Safety Officer for review (see IV.C.8, above) and postpones approval of Protocols until after review has taken place.
  3. Communicates any additional BUA requirements to the PI.
- L. Office of Research, Sponsored Programs
1. Informs the Biological Safety Officer of receipt of research proposals that indicate use of biohazardous agents for review and determination that the PI has complied with BUA requirements (see IV.C.9, above).
  2. Informs the PI of requirement to have approved, project-specific BUA in place prior to the start of research.
  3. Postpones acceptance of research funds until receipt of verification that BUA requirements are met.
- M. Facilities Operations and Maintenance
- Tests and certifies all in-place HEPA filters at the time of installation, annually, and when filter is replaced or repaired.

**V. Further Information**

Additional information on biological safety standards and BSAAC procedures is available from EH&S (530-752-1493). BUA forms are available on the EH&S Web site ([http://ehs.ucdavis.edu/biosfty/bio\\_forms.cfm](http://ehs.ucdavis.edu/biosfty/bio_forms.cfm)).

## VI. References and Related Policies

- A. UC Office of the President (<http://www.ucop.edu/ucophome/coordrev/ucpolicies/>):
  - 1. Contract and Grant Manual Section 3-400, University Policy on Biohazards and Recombinant DNA.
  - 2. University Policy on Management of Health, Safety, and the Environment.
- B. Federal Regulations:
  - 1. National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules.
  - 2. CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) Guidelines (<http://www.cdc.gov/biosafety/>).
  - 3. Code of Federal Regulations Title 42, Public Health, Sections 72 and 73 (<http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR>).
  - 4. USDA Biotechnology Guidelines.
- C. UC Davis Biosafety Manual (<http://safetyservices.ucdavis.edu/>).
- D. UCD Policy and Procedure Manual (<http://manuals.ucdavis.edu/PPM/about.htm>):
  - 1. Section 220-03, Anatomical Specimens.
  - 2. Section 290-15, Safety Management Program.
  - 3. Section 290-25, Health Services for Individuals Having Animal Contact.
  - 4. Section 290-27, Hazardous Substances Communication Program.
  - 5. Section 290-30, Use and Care of Animals in Research and Teaching.
  - 6. Section 290-35, Environmental Protection.
  - 7. Section 290-50, Protective Clothing and Equipment.
  - 8. Section 290-60, Occupational and Preventive Medicine.